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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,618

04/07/2004

Yadong Huang

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

08/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/820,618	Applicant(s) HUANG ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-20, 25-30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 17-20, 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-16 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11-29-05; 6-16-04; 4-7-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group IV in the reply filed on May 22, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Amendment filed May 22, 2008 has been entered.
3. Claims 1-6, 21-24 and 31 have been cancelled. Claims 7-11, 17-20 and 25-30 are withdrawn. Claims 12-16 and 32-37 are examined.

Specification

4. The disclosure is objected to because of the following informalities: "four groups" should be "three groups" since only three forms are listed (pp. 61 paragraph [00233]).
Appropriate correction is required.

5. The use of the trademarks Aricept, Exelon, and Cognex has been noted in this application (pp. 33 paragraph [00140]). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While claim 1 recites a preamble stated goal (modulate a phenomenon associated with Alzheimer's disease) but does not recite any method steps to fulfill the stated preamble stated purpose.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6-12 and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Crutcher and Harmony (WO 98/01101; 15 January 1998).

WO 98/01101 discloses a method of inhibiting the formation of neurotoxic apoE4 fragments in primary chick sympathetic neurons via protease inhibitors. WO 98/01101 teaches the use of antipain, a general serine protease inhibitor, to prevent the generation of toxic apoE4 fragments (pp. 15 Example 5). Furthermore, WO 98/01101

claims a method of treating conditions associated with apoE toxicity, including Alzheimer's disease, comprising administering a protease inhibitor, including antipain, to interfere with the production of neurotoxic fragments of apoE4. While WO 98/01101 is silent with respect to neurofibrillary tangles in a neuronal cell in an individual with Alzheimer's disease, the specification discloses that reducing the amount of apoE4 tangles will have this effect. Thus the effect on Alzheimer's disease is inherent to the method of WO 98/01101.

8. Claim 6-12 and 32-37 is rejected under 35 U.S.C. 102(b) as being anticipated by Tolar et al. (The Journal of Neuroscience **19(16)**: 7100-7110).

Tolar et al. discloses a method of using a protease inhibitor cocktail to attenuate the production of neurotoxic apoE4 fragments in dissociated chick, sympathetic neurons (pp. 7102 "Protease inhibitors reduced the production of truncated apoE and attenuate Neurotoxicity of full-length apoE"; Figure 1). Tolar et al. uses a protein cocktail which includes antipain, a known serine protease inhibitor. While Tolar et al. is silent on reducing the activation of an enzyme that catalyzes the formation of carboxyl-terminal truncated apoE by A β ₁₋₄₂, the specification demonstrates that said enzyme is susceptible to inhibition by serine protease inhibitors. Thus the effect on Alzheimer's disease is inherent to the method of Tolar et al. Furthermore, Tolar et al. discloses that the protease inhibition reduces the formation of neurotoxic apoE fragments thus meeting the limitations of claim 31 (Figure 1, lower panel, western blot).

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9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879.

The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Pak/
Primary Examiner, Art Unit 1646
1 August 2008